



DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TEXAS 78234-6000

June 21, 2002

REPLY TO
ATTENTION OF

Health Policy and Services

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fisher Lane, Room 1061
Rockville, Maryland 20852

Dear Sir:

We have reviewed the Draft Guidance for Industry Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires (Federal Register: 22 Jun 02, Volume 67, Number 77, Docket Number 02D0080). Overall, we concur with the intent of the draft guidance and applaud the agency's commitment to improving the efficiency and effectiveness of the donation process. Accordingly, the Army Blood Program Office would like to provide the following comments for your consideration as you prepare the final guidance.

a. Comment 1. It is our belief that self-administered high-risk behavior questions will be just as effective as orally delivered high-risk behavior questions and their use will significantly reduce the workload for our limited donor center staffs. We are concerned, however, with a specific recommendation for manual procedures listed on page 3, Section III.A.4 that states, "You should not allow new donors to self-administer the donor questionnaire." There is no data to suggest that either first time donors or repeat donors should be treated differently. In fact, a workshop conducted by the National Institute on Drug Abuse, National Institute of Health entitled, "The Measurement of HIV Risk Behaviors for Research Treatment Studies," clearly suggests that the most sensitive questions should be self-administered as they eliminate interviewer bias and are more efficient.

- Military blood donor centers rely heavily on initial entry personnel who are usually first time donors. By excluding the first time donor from using self-administered, high risk donor questions, the military stands to lose another significant portion of its donor population and will have to completely change the way donor screening is accomplished. It has been a long-standing, common practice in military and civilian donor centers to instruct donors on the proper completion of the health history, after which the donor reads and answers the

questionnaires. We believe this practice to be safe and effective as evidenced by our low number of post-donation information reports. Due to the mobile nature of the military population, the majority of our donors may donate only once or a few times at each donor center. Sometimes donor interviewers may be of higher rank than the donor. This situation may add increased complexity to the issue of face-to-face interviews and impact more severely on the questions.

b. Comment 2. Page 3, Section III.A.7 states, "You should provide the donor...You should instruct the donor to leave an answer blank if he or she does not understand a question. You should instruct the donor not to sign the questionnaire until your personnel have reviewed the document." The guidance clearly states on page 2 that this document does not address the informed consent process. When a Military donor signs the standard Military Blood Donation Record, Department of Defense Form 572, which contains donor demographics, donor history questions, and informed consent all on one document, he or she is signing an informed consent. It is unclear whether two signatures will now be required; 1) after the questions are answered and 2) for the informed consent. We request clarification so that only one signature will be required for both the donor questions and informed consent.

c. Comment 3. Page 3, Section III.A.9 states, "If you revise your questionnaire to include new or modified questions, you should administer the new or modified questions to all donors by direct oral question...". This requirement is unrealistic and unreasonable. At what point does a new or modified question become part of the routine questions and be removed as a new or modified question. All donor centers would need to have an extensive pre-donation tracking system to track which questions were provided for each donation as to current, new or modified question so that donor questions would no longer need to be administered differently from the "routine or historical" questions. We request this statement be removed from the guidance document.

d. Comment 4. We have concerns with Section III.B.5. that states, "You should monitor the donor's attentiveness and be ready to intervene if the donor appears confused or inattentive." This appears to be in direct conflict of Section III.B.6, that states, " If more than one donor is listening to or watching the recording...you should ensure that the donors have privacy when answering the questions and are not discussing answers to the questions." and with Section III.A.3 that states, "You must provide an appropriate environment for individuals to complete their donor questionnaire in a private setting." We request this statement to either be clarified or removed from the guidance document.

e. Comment 5. We have concerns with the computer-assisted interactive procedures mentioned throughout the document. These procedures are too directive and strict and do not encourage important technological advancements in donor screening. Section III.C.1. states that, "New donor may use computer-assisted interactive procedures provided there is an audio component with the system." Reading donor questions using a computer-assisted interactive procedure should not be any different than donors who are manually self-administering donor questions. We request that you re-consider computer-assisted interactive procedures to help promote technological advancement in donor screening.

Thank you for giving us the opportunity to provide comments and feedback on the draft guidance. The point of contact for this report is the undersigned, (703) 681-0360 or Ms. Kathleen Elder, Army Blood Program Quality Assurance Manager, Office of the Assistant Chief of Staff for Health Policy and Services, Ancillary Health Services Division, (210) 221-7989.

A handwritten signature in black ink, appearing to read "Gary C. Norris". The signature is fluid and cursive, with the first name "Gary" being more prominent.

Gary C. Norris
Colonel, U.S. Army
Director, Army Blood Program